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IN THIS ISSUE

FDA Admits to Error, Revises Exemption List

Citing an administrative error, the FDA has updated its list of medical device types that are exempt from premarket notification requirements.

The gaffe, according to an Aug. 14 *Federal Register* notice, occurred because agency staff failed to consider certain comments before issuing final guidance (*IDDM*, July 6). Issued last month, the guidance document exempted product codes for certain unclassified, Class I and Class II medical devices that are well understood and don't require premarket submissions to ensure their safety and effectiveness.

Among the devices named in the document were certain oscillometers, teething rings and medical support stockings.

(See **Guidance**, *Page 4)*

China Adopts New Guidelines For Medical Device Software

The China Food and Drug Administration has released guidance on the registration of medical device software, paving the way for devicemakers to register software on a standalone basis.

In the past, medical software was registered as a component of a medical device, as there were no regulations for registering standalone software, says Ames Gross, president of Pacific Bridge Medical. The new guidance allows software to be registered and sold as standalone items.

The new policy provides a clearer path to registration and is likely to boost sales, Gross tells *IDDM*. It also means that some standalone software can be used by various companies on multiple devices, he adds.

The Aug. 5 guidance, which is meant to standardize the technical review requirements of medical device software, says companies

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China, *from Page 1*

should consider the software security level in combination with its intended use and core functions. Software is divided into three levels based on potential harm, with Grade A posing little to no harm, Grade B presenting a non-serious health risk and C potentially causing death or serious injury.

The document also provides an overview of basic information developers should include in the software description, such as model specifications and release version, the software security level, operating environment and any use restrictions.

The guidance also gives an overview of software development and information on risk management, verification and validation and defect management.

The CFDA says it will update content in the document as new regulations, standards and technical capacity become available.

Read the guidelines, in Chinese, at www.fdanews.com/081715-china-software.pdf.
— Elizabeth Hollis

Device Companies Fall Prey To International Hackers

Edwards Life Sciences and San Jose, Calif.-based Align Technology, which markets the Invisalign clear braces system, were among companies caught up in a cyberplot to gain profits from stolen earnings announcements.

In a civil complaint filed Aug. 10 in the U.S. District Court for the District of New Jersey, the U.S. Securities and Exchange Commission accuses 32 defendants – both individuals and corporate entities, many with Ukrainian ties – of using stolen nonpublic information for illegal profit.

The complaint alleges that over a five-year period, Ivan Turchynov and Oleksandr Ieremenko hacked into the networks of Marketwired, PR Newswire Association and Business Wire to steal press releases detailing companies' quarterly and annual earnings data before they appeared online. The hackers then sold the releases to traders who used the information to their financial advantage.

One group of traders named in the action — consisting primarily of the family, friends and associates of Arkadiy Dubovoy, a businessman living in Alpharetta, Ga. — took in more than $31 million.

The second group consists of foreign traders, many with ties to Russia.

According the U.S. Attorney's Office for the District of New Jersey, the traders had "wish-lists" of companies for the hackers to target.

"This international scheme is unprecedented in terms of the scope of the hacking, the number of traders, the number of securities traded and profits generated," says SEC Chair Mary Jo White.

She adds the hackers and traders reaped more than $100 million in illicit profits, and their assets have been frozen.

Caught in the Crossfire

According to the complaint, the defendants stole a 2013 earnings release for Edwards, allowing traders to rake in more than $4 million in illicit profits. The ill-gotten gains from Align also come to $4 million.

If the court determines the defendants violated federal securities laws, they could be ordered to pay penalties and return any fraudulently obtained gains with prejudgment interest.

In a parallel action, authorities with the U.S. Attorney's Office for the District of New Jersey and the U.S. Attorney's Office for the Eastern District of New York have filed criminal charges against several of the defendants identified by the SEC, including Turchynov and Ieremenko and members of the Dubovoy trading group.

To read the SEC complaint, visit http://www.fdanews.com/08-17-15-ukrainian-hackers.pdf.
— Elizabeth Hollis

Regulatory Uncertainty Slows Approvals of Novel Devices

Pioneer entrants for medical devices face a steeper hurdle than their drug counterparts in gaining approval, according to research from a Harvard professor.

"[I]n contrast to the early entrant advantages observed in drug regulation, first entrants in medical device markets experience a strong disadvantage in the regulatory approval process," says Ariel Stern, an assistant professor of business administration, in *Innovation under Regulatory Uncertainty: Evidence from Medical Technology.*

Stern notes that pharmaceuticals "are a relatively homogeneous category of products," with decades of regulation. "By comparison, medical devices and other non-drug medical products are far more heterogeneous and have a much shorter history of FDA oversight."

The problem isn't technological novelty or a lack of scientific knowledge on the part of reviewers, according Stern, but a lack of regulatory guidelines — particularly when it comes to devices with new product codes.

Stern points to implantable cardioverter defibrillators, which were first approved in 1983. Starting in 1998, some ICDs obtained a new product code as a result of modifications to the device. These later ICDs still experienced a regulatory delay, even though the FDA had years of experience evaluating them. Indeed, Stern says it takes 34 percent longer for pioneer medical device entrants with new product codes to go through the approval process than successive applicants.

While the lack of explicit evaluation criteria for devices contributes to this uncertainty and lengthy delays, the issuance of guidance explaining approval criteria for specific device types often reduces approval times, Stern says. Following issuance of guidance on drug-eluting stents, intravascular stents, heart valves and catheter ablation devices, approval times dropped by approximately 6.6, 5.5, 2.8 and 4.9 months, respectively.

While large firms are facing delays, the burden is worse for smaller companies, which have fewer resources and face prohibitive capital costs trying to get novel products to market.

Many smaller companies avoid innovative work because it's too risky. Stern found that small devicemakers make up just 6.9 percent to 17.2 percent of pioneer entrants, compared with 36.4 percent to 54.5 percent in the pharmaceutical industry.

Suggestions for Improvement

Based on her research, Stern recommends the faster release of product-specific guidance documents. Earlier meetings between the FDA and sponsors could also lead to evaluation standards or guidelines before a submission is formally made.

She sees the 21st Century Cures Act as a potential avenue for restructuring the device approval process. Under the proposed legislation, devicemakers developing advanced technologies that either have no alternative or offer a significant improvement over existing alternatives could apply for a priority review designation before submitting an application (*IDDM*, May 1).

The legislation was approved by the U.S. House of Representatives last month in a 344-77 vote. The Senate is working to develop similar legislation (*IDDM*, July 10).

Stern tells *IDDM* that her research focuses broadly on the field of health economics and the economics of innovation. "The medical device industry is a place where the two fields meet, but very little academic health economics research is done," she says. "My hope is to change that a bit with a few papers on the medical device innovation/regulatory process, and this is the first one in that effort."

To read the report, visit www.fdanews.com/08-17-15-innovation.pdf. — Elizabeth Hollis

Guidance, *from Page 1*

A draft version of the guidance came out in August 2014, with a comment period closing Sept. 30. After receiving 55 comments, the FDA took a number under advisement.

For example, it added product code OYS, patient bed with canopy or restraints, among other revisions.

As it finalized the guidance, the agency also identified an additional 15 device types for the list. While some of the comments mentioned codes were not reviewable by the Center for Devices and Radiological Health, others mentioned conformance to recognized standards — something that goes beyond the scope of the guidance.

Rectifying Error

The agency eventually determined it had not taken some comments into consideration, leading to the addition of eight codes.

Newly added to the exemption list are:

- DTL — adaptor, stopcock, manifold, fitting, cardiopulmonary bypass;
- OCY — endoscopic guidewire, gastroenterology-urology;
- KOE — dilator urethral;
- FTA — light, surgical, accessories;
- GZM — analyzer, rigidity;
- GZO — device, galvanic skin response measurement;
- HCJ — device, skin potential measurement; and
- HLJ — ophthalmoscope, battery-powered.

Interested parties may comment on the guidance at any time.

Read the *Federal Register* notice at www.fdanews.com/081715-update-guidance-list.pdf. To view the updated guidance document, visit www.fdanews.com/081715-guidance-exempt.pdf.

— Elizabeth Hollis

ANVISA Touts Improvements In Inspections, Surveillance

Improving inspection activities and concentrating on postmarket surveillance to enhance patient safety are two areas in which Brazil's Agência Nacional de Vigilância Sanitária made strides in 2014, according to a new report.

The document highlights last year's ramp up of Brazil's participation in the two-year Medical Devices Single Audit Program to speed the inspection process and certification. At the beginning of 2015, manufacturers from around the world wanting to market medical devices in Australia, Brazil, Canada and the U.S. were invited to participate in the pilot program.

Overall, ANVISA carried out 158 inspections for facilities making health products. To ensure that investigators are well-trained, ANVISA introduced a distance-learning tool through the open source platform Moodle that emphasizes strengthening health surveillance. The regulator also evaluated its international inspections process with an eye toward identifying areas for improvement.

Jarbas Barbosa da Silva, Jr., who recently took the reins of the agency, released the report, *Relatório de Atividades 2014*, to the committee on Social Security and Family Brazil's House of Representatives on Aug. 6. ANVISA-regulated products represent at least 10 percent of the gross domestic product, according to da Silva (*IDDM*, Aug. 10).

ANVISA also worked on beefing up postmarket surveillance, evaluating accounts of adverse events reported by healthcare providers and the public through its National Health Surveillance Reporting System. In 2014, the agency received 13,138 adverse event reports resulting from medical items, including syringes, intrauterine devices, catheters and orthopedic implants. A separate category of medical equipment — pacemakers, infusion pumps, ventilators — drew 974 adverse event reports, while *in vitro* diagnostics saw 219 reports.

Last year kicked off on a good note for manufacturers, with a resolution allowing ANVISA to streamline the process for getting devices to market faster. The change allows the agency to accept audit reports from recognized international regulatory authorities.

ANVISA also exempted Class 1 and 2 devices from certification — although adherence to good manufacturing practices is still required. Finally, companies making higher-risk Class 3 and 4 devices don't have to wait for a GMP inspection to begin the registration or revalidation processes. — Elizabeth Hollis

India Trade Group: Bolster Components Sector to Enhance Medtech

A trade group is calling on India's Department of Pharmaceuticals to promote incentives for the country's components industry, saying doing so will help to fuel domestic manufacturing of medical devices.

Boosting micro, small and medium enterprises in the components sector would encourage Prime Minister Narendra Modi's "Make in India" program, the Confederation of Indian Industry says in an Aug. 4 document. The program aims to transform India into a global manufacturing hub for a range of industries.

"CII has emphasized the importance of recognizing the fact that the manufacturing business case in India is quite challenging," the trade group says.

"While the labor costs are lower in the country, the capital investment and productivity of the labor are critical limiting factors to the manufacturing business case. Combined with approval delays, this makes the manufacturing environment quite challenging for entrepreneurs," it adds.

To help overcome these challenges, the group recommends creating medical technology manufacturing hubs throughout the country.

The government could offer subsidized land prices to set up these hubs, as well as develop

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India, *from Page 5*

joint ventures, licensing agreements and public-private partnerships to enhance the manufacturing ecosystem.

CII singles out Singapore and Ireland as examples of countries where hubs have helped to foster innovation. Singapore's medical technology industry nearly tripled its manufacturing output from about US $1.1 billion in 2000 to about $3.1 billion in 2011.

Meanwhile, Ireland has seen tremendous success in its devices sector, which enjoys annual sales of more than $6.6 billion.

The recommendation echoes a call earlier this year by the public-private Task Force on the Medical Devices Sector in India for device hubs with common medical device testing facilities that would be funded at least partially by industry (*IDDM*, April 17).

The group also proposes low-cost capital through favorable loans and tax incentives to spur investment and lure manufacturers to India. These manufacturers would improve the components ecosystem, giving local companies access to their products.

CII also argues that the regulatory bar is set too high for devicemakers, with a Byzantine process requiring approvals from a range of agencies. Simplifying the process would help bolster the industry.

The group says that incentivizing components makers should be a higher priority than implementing the preferential market access policy for medical devices, which gives preferential treatment to domestic goods to encourage Indian manufacturing.

Currently, a PMA policy is in place for procurement of electronics and information and communication technologies by government and state-owned enterprises. — Elizabeth Hollis

House Members Call on GAO To Investigate FDA over Morcellators

A bipartisan group of lawmakers is calling on the head of the U.S. Government Accountability Office to investigate the root cause failure that led to power morcellators remaining on the market for more than two decades before being slapped with a black box warning last year.

"Hundreds, if not thousands, of women in America are dead," because of the power morcellator, which is used to remove uterine fibroids, the lawmakers say. They cite historical studies going as far back as 1990 showing the increased risk of spreading cancer in women.

"Despite these studies, as late as last year, the FDA, the medical device industry, and many gynecologists pointed to the risk of a hidden cancer as being low, only 1-in-10,000," the letter states. "How did they get it so wrong for so long?"

Morcellators came under scrutiny after the FDA issued a safety alert last year saying the instrument's blades could spread unsuspected cancers in as many as one in 352 cases.

As part of the probe into morcellator safety, the group is asking the GAO to consider several questions:

- Did the FDA's reliance on 510(k) clearance sufficiently identify morcellators' risks?
- Were medical device reporting regulations followed appropriately by manufacturers, importers, user facilities and the FDA?
- What activities or training did manufacturers provide clinicians, and what professional society standards were applied for training on the use of these devices?
- What additional steps are being taken, beyond the black box warning, to determine whether the devices are safe to remain on the market?

The Aug. 7 letter was signed by Reps. Mike Fitzpatrick (R-Pa.), Louise Slaughter (D-N.Y.), Ralph Abraham (R-La.), Rosa DeLauro (D-Conn.), Bill Pascrell, Jr., (D-N.J.), Lou Barletta, (R-Pa.), Doug LaMalfa, (R-Calif.), Anna Eshoo (D-Calif.), Jan Schakowsky (D-Ill.), Chris Smith (R-N.J.), Stephen Lynch (D-Mass.) and Rick Larsen (D-Wash.).

During markup of the 21st Century Cares Act, which passed the House last month, Fitzpatrick offered seven amendments focused on getting unsafe devices off the market, particularly power morcellators. None of the amendments made the final bill (*IDDM*, July 10).

To read the letter, visit www.fdanews.com/081715-morcellator-letter.pdf. – Elizabeth Hollis

Stakeholders: FCC Decision Will Have Impact On Patient Monitors

A recent ruling from the Federal Communications Commission could affect the operation of patient monitoring equipment in hospitals.

In early August, the FCC adopted rules that will permit unlicensed television white space devices — including Wi-Fi and Bluetooth technologies — and wireless microphones to operate on Channel 37 in the 600 MHz band, as long as they don't interfere with licensed wireless medical telemetry systems.

The vote comes as the commission prepares for a scheduled March 29, 2016, incentive auction to make available high-quality, low-band spectrum for mobile broadband.

Through these auctions, television broadcasters will go off the air, and share their spectrum or move channels in exchange for part of the proceeds from wireless providers seeking additional broadband, according to the FCC's website.

Many healthcare stakeholders have expressed concern that adequate protections would not be put in place. Commissioner Ajit Pai said the FCC assumed that hospitals with WMTS devices are no more than three stories tall. That is not the case with the majority of such facilities.

"The WMTS community is not alone in its worry," he writes. "A bipartisan group of nearly 20 members of the U.S. Senate and House of Representatives recently weighed in on this issue.

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They noted that the record includes the results of real-world testing at three different hospitals demonstrating that interference to WMTS systems will be caused by a TVWS [TV white space] device operating at the power levels and distances proposed by the commission."

To guard against potential interference, Pai has proposed that healthcare facilities be able to file a waiver request to extend WMTS protection zones to up to three times their current size. These zones will remain in effect until the FCC can determine the merits of the requests.

The medical device community also has expresses concerns. In comments submitted in March, GE Healthcare, which manufactures patient monitoring devices, said that the proposed separation distance requirements weren't sufficient to protect WMTS. The company also urged the FCC to require unlicensed devicemakers to comply with a comprehensive system of quality regulations throughout the product's lifecycle.

Ahead of the FCC announcement, Sens. Tammy Baldwin (D-Wisc.), Amy Klobuchar (D-Minn.) and Debbie Stabenow (D-Mich.) wrote to FCC Chairman Tom Wheeler urging a three-month delay to consider technical rules for the use of Channel 37 by unlicensed TVWS devices.

"Wireless medical telemetry service systems for cardiac and fetal monitoring in hospitals have long used Channel 37 to operate without interference, which could severely impact patient health and safety," the lawmakers said. "We strongly urge you to give medical technology stakeholders and the unlicensed community more time to work out a technical sharing agreement that will maintain the safe use of all devices in Channel 37."

The FCC decided against this request.

The American Hospital Association has come out against the decision, saying that if the rules aren't changed, patient safety could be compromised. "We will continue to work with Congress, the FCC and device developers to seek a remedy that puts patients first," AHA Executive Vice President Rick Pollack says.

To see the FCC report and order, visit www.fdanews.com/081715-fcc-WMTS.pdf.
— Elizabeth Hollis

FDA Workshop to Focus on Cognitive Assessment Devices

Early this summer, the FDA granted *de novo* approval to a computer-based tool to assess cognitive decline that may lead to dementia. With more companies looking to develop similar assessment tools, the FDA says it hopes to encourage innovation in this area.

To that end, the agency has scheduled a workshop for Nov. 19 and 20 to gather input on potential guidance for premarket submissions.

Day one will focus on cognitive assessment devices, which are used to determine if a patient experiencing memory loss and other symptoms needs further evaluation. Discussions for the second day will center on noninvasive brain simulation devices that deliver electrical or electromagnetic stimulation to the head to improve, affect or modify the cognitive function of an individual who is not seeking treatment for a specific condition.

In an Aug. 14 *Federal Register* notice, the agency says these devices present questions related to safety and effectiveness, as well as study design and data analysis challenges.

Topics slated for discussion include:

- Considerations for clinical study trial designs, patient populations and patient selection methods;
- Considerations for clinical study endpoints, e.g., clinically relevant outcome measures and related statistical analyses;
- Identification of risks and risk mitigation strategies; and
- Evaluation of prior studies, current clinical research and available scientific and clinical evidence.

Interested parties may submit comments on workshop topics until Dec. 5.

To read the *Federal Register* notice, visit www.fdanews.com/081715-brain-meeting.pdf. – Elizabeth Hollis

German Government Gets Tough On Corruption in Healthcare

Medical devicemakers doing business with doctors in Germany will need to exercise extra caution if a proposed anticorruption law goes into effect.

The German government has introduced a draft legislative proposal in Parliament to fight corruption in the healthcare sector. *Entwurf eines Gesetzes zur Bekämpfung der Korruption im Gesundheitswesen* is designed to ensure fair competition in the sector and maintain patient confidence in the integrity of decisions made by healthcare practitioners, explains Hans-Hermann Aldenhoff, the international head of dispute resolutions at Simmons & Simmons.

If enacted, healthcare workers could face fines and imprisonment of up to five years if they accept bribes to prescribe medical devices.

Device sales representatives could be pursued on bribery charges, and punished by fines and imprisonment up to three years.

Under parliamentary rules, second and third readings of the draft are required. It then will be forwarded to the Federal Council, which may or may not raise an objection. If it is ultimately signed by the federal president, it then will be published in the *Federal Law Gazette*. Laws take effect the day after publication.

The impetus for the measure was a controversial March 2012 decision by the German Federal Supreme Court, which found self-employed healthcare practitioners were not public officials and not subject to criminal prosecution under the German Criminal Act for accepting devicemaker incentives.

Aldenhoff says Germany doesn't have a database similar to that set up by the U.S. Centers for Medicare & Medicaid Services to track device industry gifts to physicians. However, he doesn't rule out enactment of a sunshine act in the future, as there such systems are in place in France, Denmark and elsewhere in the EU.

To read the draft act, visit www.fdanews.com/081715-Germany.pdf. — Elizabeth Hollis

BRIEFS

Wanted: Input on MDUFA Reauthorization

What do you want to see in the next Medical Device User Fee Amendments cycle? The FDA would like to hear your answer at an upcoming stakeholder meeting scheduled for next month. The meeting, slated for Sept. 15 at the agency's White Oak campus in Silver Spring, Md., is one of several designed to gather stakeholder feedback on how the FDA can improve the program. Interested parties may register by visiting www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm458184.htm. Statutory authority for MDUFA expires Sept. 30, 2017. New legislation then will be required for FDA to continue collecting user fees for the medical device program.

DexCom, Google to Form Diabetes Alliance

DexCom and Google's life sciences group are teaming up to develop a series of next-generation continuous glucose monitoring products that are smaller and less expensive than currently marketed offerings. The products will incorporate Google's miniaturized electronics platform with DexCom's sensor technology. Initially, the two will focus on disposable products for use across all diabetes markets. Under the agreement, DexCom will retain all sales and distribution rights for the products developed under this agreement. It will hand over upfront and milestone payments during development, as well as revenue-based royalties once these products are launched and have achieved a certain level of revenue.

Emphysema Treatment Gets Thumbs Up

Uptake Medical has scored the CE Mark for its InterVapor system, which uses water vapor to treat patients with heterogeneous upper lobe emphysema. The CE mark follows a multi-center randomized-controlled study of patients in Europe and Australia. According to a company statement, there are limited treatment options for patients with severe emphysema. The InterVapor platform is in testing for regional lung tumor ablation in patients with early stage lung cancer and lung metastases.

Mallinckrodt to Sell CMDS Business

Mallinckrodt is selling its global contrast media and delivery systems business to French medical imaging firm Guerbet for $270 million. The transaction aligns with Mallinckrodt's strategy to streamline its portfolio and focus resources on higher-growth, higher-margin specialty brands and its generic business, the company says. The deal is expected to close in the next few months.

Mesa Snags Sterilizer Testing Business

Lakewood, Colo.-based Mesa Laboratories has acquired most of the assets of the dental sterilizer testing business of North Bay Bioscience for $11.25 million. The bulk of North Bay's business involves weekly testing, of table-top sterilizers in the U.S. dental industry to determine if they meet federal and state standards. Mesa has retained all of North Bay's employees, including the management team, and will continue to operate the business from North Bay's Traverse City, Mich., facilities.

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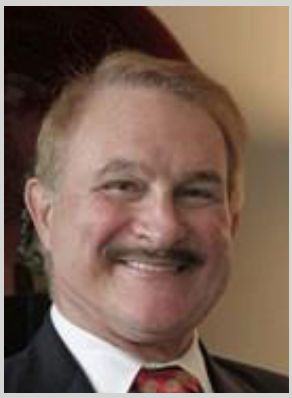

CASPER "CAP" ULDRIKS

Casper "Cap" Uldriks, founder of Encore Insight LLC provides consulting and training on FDA law and operations. Most recently he was counsel at Olsen Frank Weeda Law. With more than 30 years at the FDA he held a number of positions within the agency, such as an investigator in FDA's New England office, in the Office of the Commissioner in Legislative Affairs and in CDRH, where he served as CDRH's Associate Director for Regulatory Guidance and Government Affairs. He helped to guide CDRH to develop and implement various medical device related amendments to the Food, Drug, and Cosmetic Act, regulations and guidance documents. For years he has trained FDA staff on medical law and has been a featured speaker at many professional conferences involving FDA's medical device program.

He graduated with his B.A. in 1973 from Albion College, his Master of Divinity from Boston University in 1976, and his J.D. from Suffolk University Law School in 1986. He was admitted to the Massachusetts Bar in 1986 and the DC Bar in 2011.

OCT. 20-21, 2015 DOUBLETREE, BETHESDA, MD

Having FDA-regulated products held at ports costs time, money and your competitive edge. *But it doesn't have to.*

Instead of risking containment—or even destruction—of products, let an FDA insider show you how to implement a trouble-shooting import/export program.

Here's the one interactive workshop that arms you with a full program of today's best compliance strategies for speeding your products out of Customs and into U.S. and global markets.

No more guesswork about FDA priorities, processes or technologies; no more wondering about special provisions for trade shows, personal baggage and more. Former FDA import/export expert Casper "Cap" Uldriks lays out everything you need to know to take the risks—and delays—out of importing and exporting FDA-regulated products, including:

- How to negotiate with the FDA
- Registering and listing with the FDA
- Selecting an import broker
- FDA's and U.S. Custom's dual role
- Procedural fundamentals
- PREDICT: the FDA's computer screening program
- U.S. Custom's process and computer link to the FDA
- OASIS: the FDA's computer tracking program
- FDA automatic detention/import alert list
- Special provisions: trade shows, return for repair, compassionate use, personal baggage
- Options when your imports or exports are detained

WHO WILL BENEFIT?

This intensive hands-on training workshop is of immediate value to drug, biologics, device and diagnostics companies, as well as contract drug manufacturers, OTC companies, API suppliers, excipient suppliers, freight-forwarders and customs brokers. Personnel who will benefit the most include:

- Regulatory compliance officers
- Manufacturing directors and supervisors
- Supply chain managers
- Executive management

DAY ONE

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

9:00 a.m. – 10:15 a.m.

FDA Imports

- FDA import history and pirates
- Current legal authority
- Registering and listing with the FDA
- Selecting an import broker
- FDA's and U.S. Custom's dual role
- Procedural fundamentals
  - Required notice
  - Required information
- Documentation
  - Required and voluntary forms
  - FDA Form 2877
  - CPB Form 3461
  - Affirmation of compliance
  - Electronic Filing

10:15 a.m. – 10:30 a.m.

Break

10:30 a.m. – 12:00 p.m.

FDA's Import/Export Technologies

- FDA computer screening program (PREDICT)
- U.S. Custom's process and computer link to the FDA
  - Harmonized tariff
  - Invoice and shipping records
  - Entry number and what it means
  - Bonded warehouses for possession/control
  - FDA's notice of action and what to do
  - Sampling
  - Detention
  - Refusal
- FDA computer tracking program (OASIS)
  - Internal database
  - Violation codes

12:00 p.m. – 1:00 pm

Lunch Break

1:00 p.m. – 2:30 p.m.

Detention Process and Best Practices

- FDA automatic detention / import alert list
  - Detention by:
  - Country
  - Product type
  - Manufacturer
- Options for detained products
  - Reconditioning procedures
  - Form FDA 766 — reconditioning agreement
  - Re-export
  - Destruction and added government fees

2:30 p.m. – 2:45 p.m.

Break

2:45 p.m. – 4:30 p.m.

Group Break Out Interactive Exercises

- Import Hypothetical I — Technical Problems (short term issues)
  - What are your options if the FDA detains a product because the product code and other qualifier information is incorrect? What if the product requires a certificate of analysis? Who gets involved with the detention and what do they do? Many companies are either clueless or confused about what can to be done immediately to get the product released by FDA. What is your plan of action? Will you wing it? What are your options for storage in the meantime and what can you expect with that?
- Import Hypothetical II — Enforcement Problems (long term issues)
  - What are your options if the FDA detains your product because it is "filthy?" What are your options and what do you do? What if you tried to clean the product, but failed. Next the FDA issues you a Notice of Action for refusal. What will the FDA do and what will you do next? Your next shipment of the same product is detained for the same reason. Your boss wants an explanation and how you are going to fix the problem. What is your game plan? Quitting your job is not an option.

4:30 p.m.

Session Wrap-Up, End of Day One

DAY TWO

8:30 a.m. – 9:00 a.m.

Continental Breakfast

9:00 a.m. – 10:15 a.m.

Interacting with the FDA

- How to negotiate with the FDA
  - What to say and what not to say
  - How to set up a telephone call or face-to-face meeting
  - How to prepare for and conduct yourself at a meeting with the FDA

10:15 a.m. – 10:30 a.m.

Break

10:30 a.m. – 12:00 p.m.

Managing Import Problems with the FDA

- Mitigating regulatory risk and FDA enforcement damage
  - Shipping strategies and cargo options
  - Foreign supplier options
  - Third party laboratories
  - Insurance
- Inspection of foreign manufacturers
  - Third party audit
  - FDA inspection
- Foreign inspection damage control
  - Responding to FDA's inspectional observations ("Form FDA 483")
    - When to respond
    - What to say and not say
    - Verification
  - Responding to the FDA's warning letter and manage automatic detention
    - When to respond
    - What to say and not say
    - Documentation
    - F/U inspection by the FDA

12:00 p.m. – 1:00 pm

Lunch Break

1:00 p.m. – 2:30 p.m.

FDA Exports

- Legal authority
  - Adulteration and misbranding exemption
  - Criteria requirements for using the export exemption
    - Basic criteria (Sec. 801(e)(1) of the FD&C Act)
    - New criteria and Tier I countries (Sec. 802 of the FD&C Act)
    - Special criteria for high-risk products that do not meet new export criteria (Sec. 801(e)(2) of the FD&C Act)
- Export certificates
  - Types and qualifications for use
  - How to obtain an export certificate

Group Break Out Interactive Exercises

- Export Hypothetical I — Selling a Recalled Product Abroad
  - Your firm's recalled some OTC product in the U.S. because the instructions for use on the label left out storage instructions. You have lots of this product in your warehouse just waiting to be shipped. What are your options?
- Export Hypothetical II — Shipping a Product Abroad Before Approval by a Foreign Country
  - Your new prescription product is made for your market in France. You expect to receive your CE mark in a few days. What

continued

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Workshop Agenda | Day 2 (cont.)

will you do with the product now? Your next market will be Japan and you expect approval in a few months. What can you do now? To your surprise, France does not issue a CE mark and a cargo ship will arrive in France in about 1 week. What will you do now? This shipment was valued for $2,000 when it left Miami, now it is worth a token amount of $1,000. What are your options.

2:30 p.m. – 2:45 p.m.

Break

2:45 p.m. – 4:30 p.m.

FDA Import-for-Export

- Purpose and legal criteria
- Foreign Trade Zone status is for U.S. Customs, not FDA
- Procedures
  - Notification
  - Accountability
  - What is the "for further processing" criteria mean?

FDA's Special Import Provisions

- Trade Shows
- Return for Repair
- Compassionate Use
- Personal baggage

4:30 p.m.

Adjourn Workshop

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