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IN THIS ISSUE

FDA Appropriations Bills, Reports Detail Congressional Wish List

Ensuring that the FDA prioritizes inspections of overseas device manufacturers is one of the many tasks the House and Senate direct the agency to undertake in their respective fiscal 2016 funding bills and reports.

For example, China takes center stage in the report of the Senate bill, S.1800, which calls for stepped up efforts to ensure the safety of products imported from that country. "The Committee is concerned about the FDA's ability to keep pace with the exporter universe and volume of exports," the report says. It praises the agency for its move toward a targeted, risk-based approach to inspections, adding that funds provided through the China Safety Initiative should boost onsite verification support.

The Senate report also trumpets the advantages of *in silico* trials, which use computer models to predict how devices will behave

(See **Appropriations**, *Page 2)*

EMA to Review Medtronic Implant in Wake of Inspection

The European Medicines Agency is seeking information on an implant sold by a Medtronic unit after inspectors determined that a U.S.-based supplier of an active substance for the product had deviated from good manufacturing practices.

Specifically, the EMA's Committee for Medicinal Products for Human Use is asking Medtronic BioPharma, which is based in the Netherlands, how the findings from an April inspection of an Integra LifeSciences facility in Plainsboro, N.J., affect the risk-benefit balance of InductOs. The implant is used to treat patients with spinal disc problems and leg fractures.

The implant kit includes a powder that contains dibotermin alfa, a solvent, as well as an absorbable collagen sponge, an excipient.

During the inspection, investigators from the Netherlands and Spain found that the Intergra facility didn't have adequate measures in place

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when deployed in the general population. "In silico trials may potentially protect public health, advance personalized treatment, and be executed quickly and for a fraction of the cost of a full scale live trial," according the bill's report.

In addition, the Senate report praises the nine FDA-funded Pediatric Device Consortia for helping develop more than 450 proposed pediatric medical devices since 2009. These devices help meet unmet needs in this patient population. The report calls on the agency to fund the program "at the highest possible level within available resources" and at least at the same level as last year.

The House bill, H.R. 3049, and its accompanying report, H. Rept. 114-205 do not mention any of these initiatives involving device manufacturers. However, the House is asking the FDA to approve a change to the mammogram patient and physician reports to include information on breast density. The request comes four years after the agency's National Mammography Quality Assurance Advisory Committee approved this measure. The House report calls on the FDA to detail progress made no more than 60 days after the act goes into effect.

The Senate report also touches on this topic, but does not provide a timeframe for completing the task.

In addition, the House report takes the FDA to task for not moving forward on guidance issued in December 2011 intended to help the agency in examining policies for off-label uses of approved and investigational devices. In June 2014, the agency responded to two petitions requesting clarification onregulations regarding communications related to investigational new devices and potential off-label uses. The FDA promised by the end of that calendar year to issue guidance addressing, among other things, the distribution of scientific and medical information on unapproved new uses.

The House report orders the FDA to address the issue "comprehensively" and to complete guidelines within 60 days of act going into effect.

To read the Senate bill and report, visit www.fdanews.com/072015-senate-appropriations.pdf and www.fdanews.com/072815-SRpt114-82.pdf. The House bill and report are here: www.fdanews.com/06-24-15-appropriations-bill.pdf and www.fdanews.com/072815-HRpt114-205.pdf. – Elizabeth Hollis

Proposed WTO Tariff Cuts To Include Medical Devices

Members of the World Trade Organization have signed a $1.3 trillion trade deal that would eliminate tariffs on more than 200 information technology products, including pacemakers and other essential medical devices.

"The (Information Technology Agreement's) expansion is great news for the American workers and businesses that design, manufacture, and export state-of-the-art technology and information products, ranging from MRI machines to semiconductors to video game consoles," U.S. Trade Representative Michael Froman says in a prepared statement.

In addition to MRI machines and pacemakers, medical devices covered in this agreement include ultrasound machines, computed tomography scanners, certain ophthalmic instruments and appliances, and electrosurgical or electromedical instruments and appliances.

Gregory Sorenson, MD, president and CEO of Siemens Healthcare North America, says the expansion of the ITA "will have not only a direct impact on doctors and patients by improving access, but also will enable companies like Siemens to invest more in R&D, American jobs, and the U.S. economy," according to a Medical Imaging & Technology Alliance Statement.

The majority of the tariffs will be eliminated within three years, with reductions beginning in 2016. By the end of October, each member will submit to the other participants a draft schedule explaining how the terms of the agreement will be met. Participants will consult with one another over the coming months with an eye on wrapping up technical work by the Nairobi Ministerial Conference in December. — Elizabeth Hollis

FDA Workshop Examines RASD Challenges, Opportunities

With surgeons using robotically assisted surgical devices in new ways, the FDA wants more information on how to best assess these tools to ensure the safety of patients while enhancing innovation.

To that end, academics, clinicians and members of industry gathered last week at the FDA's White Oak campus in Silver Spring, Md., to discuss questions related to interoperability, training and differentiating between general use and specific indications of RASDs.

William Maisel, deputy director for science and chief scientist at the FDA's Center for Devices and Radiological Health, noted that healthcare providers are using devices in ways that the agency hasn't thought of or off-label, adding that it would be a shame to not learn from these real-world examples. One way to capture lessons is through a national or international registry.

Currently, Intuitive Surgical's da Vinci system is the only RASD marketed in the U.S. Its latest model, the SP999, was introduced last year. With more devicemakers looking to enter the RASD market in the coming years, the complex technology will pose regulatory challenges for the FDA, according to an agency white paper released ahead of the meeting.

This complexity only will increase with time, and the current definition of the technology is too narrow and will become "less useful," as developers forge ahead with innovative products, according to Russell Taylor, PhD, the John C. Malone professor of computer science at The Johns Hopkins University.

While some might view this growing complexity as potentially leading to more adverse patient events, workshop presenter Daniel Herron, MD, professor of surgery at the Mount Sinai Hospital, didn't agree. "All you need is a clamp, scalpel or a needle driver to cause great harm," he said.

Indeed, the white paper pointed to many benefits of using the technology versus other surgical methods, including increased precision and accuracy of motion.

The general consensus was that the bar should not be set too high in terms of getting new RASDs to market. "It's going to be interesting to see how new robotics will be judged," said urologist Vipul Patel, MD, professor of Urology at the University of Central Florida College of Medicine.

Da Vinci was cleared by demonstrating substantial equivalence to laparoscopic devices. Patel wondered if getting new RASDs to market would be difficult if they had to prove substantial equivalence to da Vinci due to intellectual property and patent concerns. He expressed reservations about too many regulatory burdens impeding innovation: "That's not good for us in the long term," he said.

Data Collection

As part of the workshop, the FDA was interested in gathering input for approving indications for specific procedures and general use. The FDA generally considers new, specific indications to fall within the scope of the cleared general use, though they should be supported by additional preclinical, animal, literature or clinical data.

Myriam Curet, MD, a surgeon and chief medical officer at Intuitive, said that general indications don't necessarily mean anything to healthcare professionals. She suggested a proposed paradigm through which a general indication could be supported by data on specific procedures most representative of the indication as a whole.

Steven Schwaitzberg, MD, professor and chair, department of surgery at University at Buffalo School of Medicine and Biomedical Science, said data collection may be necessary to support specific procedures, such as adding a pediatric indication.

To read the FDA's white paper on the topic, visit: www.fdanews.com/072015-robots-surgery.pdf.
— Elizabeth Hollis

Getting CAPA Right: One Expert's Thoughts

Inadequate investigations and corrective and preventive actions have been one of the top reasons for 483 observations since 1997, says James Vesper, president of LearningPlus. A 30-year veteran in the pharma business, Vesper explains how to develop a successful CAPA program to uncover root causes of quality failures.

Question: *Why are having adequate CAPA procedures such a problem for firms? Is it lack of understanding of FDA regulations?*

Answer: It's mostly not understanding regulator expectations, and the expectation is to do a thorough investigation to get to the root cause. A lot of companies will say the reason they had an error or failure was due to human error, and they often leave it there. But regulators around the world would say that human error is not a root cause – it's a category – and they expect the firm to delve into that more deeply.

Saying that it's human error begs the question of why. Did people not understand the procedure? Did they violate the procedure? Why did they violate the procedure?

One of the mistakes companies will make is to tell the FDA investigator that the solution is either to retrain the operator or rewrite the procedures. The FDA is pushing back on this because it says companies are using "retraining the operator" as a default approach, and "retraining" often signals an inadequate investigation.

Q: *How can management help change that?*

A: Number one, they need to support doing a thorough investigation, which takes time. The FDA has the expectation that investigations will be completed in 30 days, but it wants companies to get to the root cause even if it does take a bit longer. If it takes longer — 45 to 60 days, for example — the caveat is companies need to provide interim reports to their quality units to keep them up to date on what is going on, what the issues are and what they are doing to protect the product and the patient.

Q: *When does a firm need to initiate a CAPA? Does it need to do so for just one out-of-specification result?*

A: Yes, for an OOS result, a company needs to initiate a CAPA investigation and then decide what to do. Sometimes you can rework something, but sometimes you have to reject the device.

Q: *What are the elements of a well-written report?*

A: First is the problem description, which will help you get to the root cause. Another element is determining the scope and impact. What products and lots were affected? The impact assessment is whether the problem has a negative effect on the patient or device availability.

Using problem-solving techniques, you can conduct a thorough investigation to get to the root cause. Sometimes you may not get to the root cause, but you need to be able to demonstrate what you did and what type of monitoring you will institute, so if the problem happens again, you'll be in a better position to get to the root cause.

Finally, companies need to determine appropriate corrective action and show that it has a positive impact on the problem.

(See **Vesper***, Page 6)*

Vesper, *from Page 5*

Q: *In reading Form 483s and warning letters, it appears that companies often don't investigate other lots when there is a failure. Is that a red flag for the FDA?*

A: Yes, and companies will always be put on the defensive by the investigator to answer how they can prove the problem only occurred in that lot. Another red flag is not having a rationale or justification on what the firm ruled out. For example, how do they know it was not the raw material that caused the problem?

Q: *Can inspections that go poorly also be an opportunity?*

A: Definitely. I worked with one company that was having lots of regulatory problems, and the quality control manager spent a lot of time talking with the lead FDA investigator. She said she learned more from that investigator in two weeks than she had in the previous 10 years.

If a company has a bad inspection that's related to investigations and corrective actions, it should look at its overall system and see if it has defined risk assessment points to triage the trivial from the significant.

[Editor's note: Want to know more about how to conduct a thorough CAPA investigation? Don't miss the ***Conducting Advanced Root Cause Analysis and CAPA Investigations*** *workshop, Sept. 16-17. For more information, visit: http://www.fdanews.com/capapc .]*
— Tamra Sami

Senate Bill Would Speed Device Access for Seniors

A bipartisan group of U.S. senators is hoping to ease access to innovative devices for Medicare patients through the creation of self-pay arrangements with their healthcare providers.

Sen. Rob Portman (R-Ohio) introduced the Accelerating Innovation in Medicine Act of 2015, S. 1757, with cosponsors Sens. Martin Heinrich (D-N.M.), John Thune (R-S.D.) and Michael Bennet (D-Colo.) that would allow devicemakers to designate products to be excluded from government payment programs at an early stage of production. The group says it will increase patient access to medical devices and save taxpayers money.

"The current medical device process is cumbersome and limits access to innovative devices and procedures for seniors who are willing to pay out of pocket," Portman says in a prepared statement. "Our bill simply allows seniors to take government out of the equation by purchasing these devices themselves rather than through Medicare. Ultimately, it will help to ensure patients and physicians have access to the most innovative medical technologies."

As written, the bill would allow device companies to provide written consent to the FDA to have their products placed on the AIM list when they submit applications for approval or clearance. A device will be on the list for an initial three-year period and remain posted for subsequent three-year periods. To keep its device on the list after the initial period, a company would have to submit published or publically available data on clinical studies completed for the product.

HHS shall maintain the list and make it available to the public, updating it at least monthly, according to the bill.

A companion piece of legislation, H.R. 2597, was introduced in June by Rep. Erik Paulsen (R-Minn.), who was joined by cosponsors Reps. Ron Kind (D-Wisc.), John Shimkus (R-Ill.) and Mimi Walters (R-Calif.). It has been referred to the Committee on Ways and Means, as well as Energy and Commerce.

Read the bill here www.fdanews.com/08-03-15-senatebill.pdf. — Elizabeth Hollis

Group Advances Ideas to Improve Medical Device Availability

A group of former U.S. lawmakers is encouraging Congress to remove barriers to accelerating the development of medical devices for unmet needs.

Advancing Medical Innovation for a Healthier America, authored by members of the Bipartisan Policy Center, outlines four primary areas of recommended policy actions for enhanced access to both medical devices and drugs:

- Improving the medical product development process;
- Increasing regulatory clarity;
- Strengthening the FDA's ability to carry out its mission; and
- Increasing investment in medical products to address unmet and public health needs.

"Americans cannot afford to rely on 20th century methodologies when the world is on the cutting edge of new health technologies," BPC co-chairmen ex-Sen. William Frist, MD, and former Rep. Bart Gordon say in an introductory letter. "The hardworking FDA employees must be given the tools and support they need to succeed in this rapidly evolving field."

Among the report's recommendations is clarifying and allowing the increased sharing of scientific information related to the off-label use devices with healthcare professionals. As part of this provision, the FDA would clarify how manufacturers can disseminate truthful information about a device that is not included in approved labeling for the product.

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InductOs, *from Page 1*

to prevent particle contamination of the sponges, which remain in the body until they are degraded. The investigators recommended that importation of InductOs into the EU be halted and Integra's GMP certificate withdrawn.

The action could lead to a shortage of the product in the EU starting in October, the EMA says.

The findings follow a January 2014 inspection of the Integra facility that turned up numerous GMP violations, with the main concerns being particulate contamination and sterility assurance. The company created a corrective action plan that was rejected. Integra sent a new plan the following month that was accepted, resulting in the receipt of a restricted GMP certificate that was valid until January 2015.

In the wake of the most recent inspection, Integra submitted a follow-up corrective action plan that was received in June and subsequently rejected due to a lack of clarity on the nature and extent of the contaminants. "Metal fragments, salt residues, hairs and PVC fibers are identified, but for none of these the most likely source has been established," according to a statement of noncompliance with GMP. No new GMP certificate was issued.

To assess whether a change to InductOs' marketing authorization is needed, CHMP is reviewing the inspection findings on the product's overall risks and benefits. The committee has asked Medtronic for a timeline of steps it intends to take to ensure the manufacturing of ACS will be GMP-compliant again, including specific measures Integra already has undertaken.

In addition, the Committee wants information on the number of batches available in the EU and vulnerable subpopulations treated with the product that should receive priority treatment.

A Medtronic spokeswoman tells *IDDM* that the company takes the findings seriously, adding that the EMA has said that there is no current indication of risk to patients and no product recall.

She says that the EMA has informed healthcare professionals that they should use InductOs per the instructions and that any product they currently have or will receive may be used.

"Medtronic BioPharma is working closely with Integra LifeSciences in an advisory capacity to develop an action plan to remediate the quality issues in a timely manner," the spokeswoman tells *IDDM*. "At this time, there is no impact to any regions outside the EU or Switzerland."
— Elizabeth Hollis

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In addition, Congress should require the FDA to establish a clear process for recognizing medical device standards and publish guidance on the topic. The agency also should commit to the harmonization of international standards, including those related to manufacturing facilities.

The FDA also should evaluate and prioritize use of real-world evidence to support post-approval study requirements and should engage stakeholders in this process, according to the report's authors.

The report adds that Congress can help improve the agency's internal review process by developing an interagency education and training program, as well as establishing a monitoring system to track progress on device review times.

Device reviews also can be improved by using public/private partnerships to augment internal resources, according to the report. These resources can help with the understanding of and access to more and complex technologies.

To read the report, visit www.fdanews.com/080315-innovation-fda.pdf. — Elizabeth Hollis

ANSM Aims for Better Surveillance, Enhanced Training

French health officials have promised to beef up surveillance of medical devices as part of a multi-year action plan released late last month.

Dominique Martin, director general of the Agence nationale de sécurité du medicament et des produits de santé, signed off on the plan that details four specific strategies to enhance health by 2018. These strategies are guaranteeing the safety of products throughout their lifecycle; promote rapid access to health products; encourage better communications with stakeholders; and make the agency more efficient and modernized.

The report, titled *Contract D'Objectifs et de Performance*, examines 12 targets and 22 specific actions the ANSM intends to take over this time period. The agency intends to focus on improving products by analyzing medical device data, monitoring clinical trial applications, examining advertising and obtaining information from other European competent authorities. It has promised to strengthen its inspection capabilities both in France and other countries.

In addition it will work with institutional partners to develop a common policy to exchange information on surveillance of products relevant to the agency. It will also ensure appropriate communications with healthcare professionals about the agency's mission.

The agency is stepping up efforts to optimize the review of medical products. As part of that plan, it will work to train reviewers to ensure they have the appropriate scientific expertise and encourage employees to update their skills to review the dossiers of increasingly complex products.

To read the full report in French, visit http://www.fdanews.com/08-03-15-france-report.pdf. — Elizabeth Hollis

Medical Device User Fees On the Rise for FY 2016

Devicemakers looking to get new products on the market should prepare to shell out more money in fiscal year 2016, as user fees for all types of applications are rising.

The new fees are as follows:

- Standard fee for PMA, $261,388;
- Panel-track supplement, $196,041;
- 180-day supplement, $39,208;
- Real-time supplement, $18,297;
- 30-day notice, $4,182;
- 510(k), $5,228;
- 513(g) request for classification information, $3,529;
- Annual periodic reporting fee for Class III device, $9,149; and
- Annual registration fee, $3,845.

Fees for 510(k)s will be $210 higher than the current fiscal year, while those for PMAs will jump $10,493. Fees for panel-track supplements also will rise sharply to $196,041 from $188,171 in FY 2015. Total revenue for FY 2016 is $129.3 million, according to an Aug.3 *Federal Register* notice. For FY 2015, base revenue was $125.8 million.

Small businesses — defined as enterprises with gross receipts or sales of no more $100 million for the most recent tax year — may be eligible for reduced fees. For example, qualifying businesses would pay $65,347 for their PMAs.

Those businesses with gross sales or receipts of no more than $30 million may also qualify for a waiver of the fee for the first premarket application (PMA, PDP or BLA) or premarket report.

Entities that won small business status in FY 2015 must requalify this year to maintain this designation. The notice contains instructions on how both foreign and domestic businesses may apply for this status.

The fees will apply from Oct. 1 through Sept. 30, 2016.

To read the *Federal Register* notice, visit www.fdanews.com/080315-user-fee.pdf. A guidance document providing additional details on user fees is available at www.fdanews.com/080215-guidance-fees.pdf. — Elizabeth Hollis

BRIEFS

MHRA Cautions on Needle Breakage

The UK's Medicines and Healthcare products Regulatory Agency is advising that those using steel cannula infusion sets manufactured by Unomedical to check them before and after use. The agency says there is a small risk that the needle could break, resulting in the leakage of medication. Found in clinical and home settings, the infusion sets are used to treat diabetes, Parkinson's disease and chronic pain. According to an MHRA announcement, the following steel cannula infusion sets are affected: SURE-T, SURE-T Paradigm, Contact Detach, Contact, Sub Q, Neria, Neria Detach, Neria Multi and Thalaset.

EMBA Medical Scores CE Mark Hourglass

Dublin, Ireland-based EMBA Medical has received the go-ahead from EU authorities to market the Hourglass peripheral embolization plug. "This is the first integrated, over-the-wire device designed for peripheral embolization procedures," says EMBA CEO George Wallace, in a prepared statement. "The goal with over-the-wire design is to provide physicians with an accurate, stent-like delivery of the device in the vessel." The device is not approved for sale in the U.S.

FDA Blesses ReShape System

Obese patients in the U.S. soon will have a new noninvasive treatment option. The FDA has signed off on an integrated dual balloon system from San Clemente, Calif.-based ReShape Medical. The device is delivered into the stomach through a minimally invasive endoscopic procedure that can be completed in 30 minutes or less. The temporary device should be removed six months after insertion. It is indicated for weight reduction in obese adult patients with one or more obesity-related condition and who have failed previous attempts at weight loss through diet and exercise alone.

Details Emerge about J&J/Google JV

Indian competition authorities have given their blessing to a joint venture between Johnson & Johnson's Ethicon unit and Google to advance the development of robotically assisted surgical devices. Dubbed Warren Robotics, the collaboration first was announced in March. At the time, neither the name of the JV nor the financial details were disclosed. The Indian authorities determined that because the assets being contributed were entirely outside the country and there were no horizontal or vertical overlaps, there would be no adverse effects on competition.

MeMed Gets Grant from EU Initiative

Israel's MeMed has scored a $3.3 million grant from the European Commission to support the development of its Respiratory ImmunoDx project. Provided by the commission's Horizon 2020 Small and Medium-Sized Enterprise Instrument initiative, the grant gives funding for products that potentially could affect the EU economy and global healthcare. MeMed will use the money to ensure the second-generation ImmunoDx can take measurements of a patient's immune response to infection at the point of care, and to fund a multicenter study evaluating the device for patients with lower respiratory tract infection.

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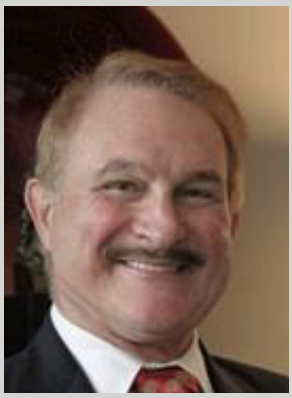

CASPER "CAP" ULDRIKS

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

☐ **Yes!** Sign me up for the **Successful Import/Export Programs**

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Room rate: $209 plus 13% tax
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