October 15, 2019

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Last month, I covered "How Does Marijuana Affect the Brain and Body?" If you missed last month's article, click here to read it. This month we'll cover "Regulatory Updates: Some Good News and Additional EU Requirements"

Read on to learn more about this topic and other current news in the Table of Content below. The next newsletter will be published on November 15th, 2019.

We encourage you to share this newsletter with your colleagues by using the social media icons below, or by simply forwarding this newsletter or use the link below. Should you or your colleagues want to join my mailing list, click on the link below.

Sincerely,
Regina Au
Principal, New Product Planning/
Strategic Planning Consultant
BioMarketing Insight

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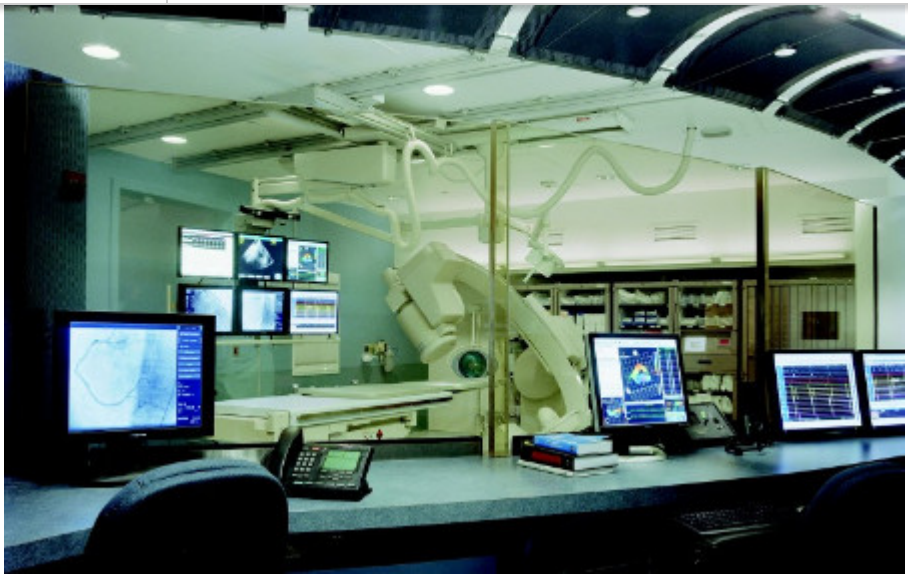

Developing a Product? Commercializing a Product?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact me for an appointment. For successful commercial adoption of your product or looking to grow your business, contact me for an appointment.

For more information on our services, click on the links below:

Product Development
Market Development
Marketing Strategies

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NECINA 紐英倫中華資訊網路協會 New England Chinese Information and Networking Association

Eight Traits an Entrepreneur Needs to be Successful.

I am pleased to announce that I was a guest speaker at NECINA's Youth Entrepreneurship Services (YES), a program for high school students to develop entrepreneurship and leadership skills and encourage interests in science, technology, and engineering on Saturday, October 12th, 2019. I spoke on the topic "Eight Traits an Entrepreneur Needs to

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Asian American Women in Leadership Conference

I am pleased to announce that I will be conducting a workshop at the Asian American Women in Leadership Conference on Saturday, November 16th at Simmons University. For more information on the conference, click here.

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Microbiome Therapeutics US

Developing a Successful Microbiome Commercial Strategy

I am pleased to announce that my article entitled "Developing a Successful Microbiome Commercial Strategy" was published in the KNect365 Magazine under the heading of Next Generation Therapeutics. This is a sneak preview to my presentation on Wednesday, September 11, 2019 at the Microbiome Therapeutics conference at the Boston Convention Center. To read my article, click here. To attend the conference, click here.

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International

Why Conducting Marketing Due Diligence Early in Product Development Is Important

I am pleased to announce that my article entitled "Why Conducting Marketing Due Diligence Early in Product Development Is Important" was published in the BioProcess International Magazine. To read the article, click here.

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3D Medical Printing Potential

I am pleased to announce that my article on 3D Medical Printing, Printing Potential has been published in the April 2019 issue of *Innovations in Pharmaceutical Technology* (IPT). This article reviews where 3D printing is the most beneficial and why. To read the article, click here, p26-29.

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Regulatory Updates: Some Good News and Additional EU Requirements

The FDA has made great strides in working with industry in developing new programs and guidance for expediting the approval of life saving drugs and medical devices particularly in the area of oncology and rare diseases in the last ten years.

They are continuing this momentum with additional programs and guidance that are outlined below for drugs and devices:

Drugs

1) Project Orbis:

In order for drug manufacturers to sell their product globally, they need to get drug approval from each country except for the EU which often occurs in succession. Each country has a different review process resulting in the delay of drug approval and patient access.

The FDA Oncology Center in conjunction with Health Canada and the Australian Therapeutic Goods Administration led a pilot program called Project Orbis to collaboratively and simultaneously review and approve drug applications in their respective country for oncology drugs.

For the first time, all three country's regulatory body has approved two cancer drugs, Merck & Co.'s immunotherapy Keytruda, in combination with Eisai's Lenvima, for the treatment of

"As Project Orbis expands, we look forward to welcoming additional international partners (such as the European Medicines Agency) to collaborate with us in this important initiative," said acting FDA Commissioner Ned Sharpless.

"The FDA's review of Keytruda plus Lenvima also benefited from another FDA pilot project called "Real-Time Oncology Review," which permits submission of data prior to the completion of an entire clinical application.

The FDA said future collaborations could also involve New Drug Application or Biologics License Application but stated that these reviews "may be more complex due to proprietary information involved."

2) Three-stage Process for Product Development and Pre-submission meetings for ANDAs:
There is a new Manual of Policies and Procedures (MAPP) for handling product development and pre-submission meetings for ANDAs.

The agency will grant a meeting for products that have no product-specific guidance or an “alternative equivalence evaluation.” Depending on its resources, the agency may grant a product development meeting if it involves topics that the agency feels would significantly improve ANDA reviews.

An applicant can request a meeting using the CDER Next Gen Collaboration Portal or by contacting the Office of Generic Drugs via email. If a meeting request is granted, the agency’s project manager will notify the applicant within 14 days.

Medical Devices

1) Two-week 510(k) reviews?:

510(k) product reviews from new breakthrough devices and pre-submission programs, to normal safety-focused innovations and established device types with the mission to increase engagement early in the process to avoid potential problems down the road.

Many of these options may be achievable to get the process ".....down to 90 days—but suppose you would like to have a 510(k) reviewed in two weeks?" posed the agency's Device Evaluation director, Jeffrey Shuren. "Well, that requires a different solution."

More than anything else, it's a capacity issue, Shuren said.

"It's an engineering problem. It's that we receive between three and four thousand 510(k)'s per year—not to mention all the PMAs and supplements and de novos," he said. "The reviewers have lots of other stuff on their desks."

While the industry has, at times, criticized the agency's efficiency, "the issue is that we can't expect the FDA to do things faster if we (manufacturers) don't do things better," said panel member Susan Alpert, principal of SFA Consulting and formerly a senior vice president at Medtronic and director of the FDA's Office of Device Evaluation. This includes not making full use of the agency's available program and presenting their product and data in ways reviewers can easily understand.

Industry has to take responsibility in doing their part. When it comes to submissions, helping reviewers connect the dots in the data and making the information easily searchable is just as important, Shuren said, especially in the move to electronic filings.

"So if you want to be successful with us, one is we have to understand your technology," Shuren said. "Don't just give us a bunch of schematics, quite frankly—show us the technology. You can do a video. Walk us through it, and let us really understand it. And then, secondly, tell your story."

To help expedite the flow of submissions, the FDA has mandated the use of templates in 510(k) reviews since late 2015, and assists reviewers building product evaluation information in the form of memos and links to relevant agency guidance documents.

"Now we're looking at building something similar for industry, on electronic submission templates, to walk them through what to do," Shuren said.

2) E-submissions:

In accordance to the *FDA Reauthorization Act of 2017 (FDARA)*, the US Food and Drug Administration (FDA) on September 25, 2019 published a new draft guidance with "both binding and nonbinding provisions" related to electronic submissions for medical devices.

and Cosmetic Act (FD&C Act) to revise and extend the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

FDARA requires FDA to develop several different kinds of informational documents, including public reports, reports to Congress, communications plans, and others. FDA will post these items as they become available.

In addition, the guidance will specify the formats for specific submissions and corresponding implementation timetables.

“Specifically, this guidance discusses (1) the submission types that must be submitted electronically, (2) the timetable and process for implementing the requirements, and (3) criteria for waivers of and exemptions from the submissions in electronic format requirements,” the draft explains.

Electronic submissions are required for 510(k) submissions, De Novos, Premarket approval applications (PMAs), modular PMAs, product development protocols, investigational device exemption (IDE) applications, humanitarian device exemption applications, emergency use authorizations, and certain investigational new drug applications and biologics license applications, FDA says. And although they’re not required, FDA recommends all Q-submissions be submitted in electronic format.

3) EU Medical Device Regulation (MDR), Safety or Biocompatible Standard Requirements:

Whether manufacturers are currently selling products or are planning to sell their products in the EU, they must abide by the new safety or biocompatible standard requirements. This regulation goes into effect May 2020 and requires CE mark for product that may have not required CE mark prior to this effective date.

The new guidelines have stricter requirements in some areas requiring additional testing that could take a significant amount of time to perform. Companies need to plan for this extra time and expense to avoid delays in approval.

The following are key changes to these regulations:

1) Companies are no longer grandfathered in for their devices and all devices must prove that their devices are biocompatible without relying on historical data for safety no matter how long the product has been on the market.

2) The Medical Device Regulation (MDR) also regulates the production facility environment and the additives that are used in the manufacturing and design of the device. The MDR stipulates that no carcinogens, mutagens, and reproductive toxic substance (CMR) can be

than 0.1% weight by weight (w/w).

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Closing Thoughts

Sometimes the mere mention of FDA puts some people on edge. They think of the FDA as being structured, ridged, and bureaucratic. And while this may have been true ten years ago, the leaders of the FDA such as former FDA Commissioner Margaret Hamburg, Jeffrey Shuren, Janet Woodcock, and former FDA Commissioner Scott Gottlieb have made great stride in changing the image of the FDA to what it is today.

The FDA has made every effort to work with industry in trying to develop programs that will approve drugs and devices quicker yet not compromise safety and efficacy. The initiative for Project Orbis is a great example of trying to expedite cancer drug approvals across multiple international regulatory bodies simultaneously and this is just the beginning. Dr. Shuren's programs for shortening device approval to 90 days is also an accomplishment.

The FDA is also more willing to meet with companies earlier in the product development process to guide these companies to be on the right track. Although the process to develop these programs may seem slow, it's quite fast considering how slow government can move due to bureaucracy. All-in-all, things are getting better and moving in the right direction.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition, target product profile and economic value of your product for reimbursement, feel free to contact me at 781-935-1462 or regina@biomarketinginsight.com.