Stakeholder Consultation Meeting on MDUFA V Reauthorization
January 26, 2022, 1:00-1:45 PM
Virtual via Zoom

Purpose

To continue the process of FDA periodic consultation with representatives of stakeholder groups. During this meeting, FDA provided updates on the progress of the negotiations with industry and presented a summary of the CDRH 2021 Annual Report.

Meeting Start Time: 1:00 PM

Update on Industry Negotiations

FDA communicated that no negotiation meetings occurred since the last stakeholder consultation meeting, and that the next negotiation meeting is scheduled for February 3rd.

CDRH Annual Report

In an effort to share the broader work CDRH has been doing beyond MDUFA IV commitments, FDA provided a brief preview of information from the CDRH 2021 Annual Report. The report is a high-level, consumer-friendly summary of CDRH's programmatic accomplishments and metrics over the past year.

First, FDA highlighted some of the accomplishments from 2021 in promoting device innovation, including 103 novel devices receiving FDA marketing authorization, and 213 products being designated as breakthrough devices, bringing the total breakthrough device designations to 617 since program inception. FDA pointed out that this increased interest in the breakthrough device program, which has helped to fuel marketing authorization of novel devices, also contributed significantly to increases in CDRH's workload.

With regard to patient engagement, FDA highlighted the incorporation of additional patient reported outcome (PRO) measures into regulatory decision making, as well as an October Patient Engagement Advisory Committee meeting to discuss and make recommendations on FDA's medical device recall approach. In addition, FDA noted the recent release of two key guidances related to patient engagement in the design and conduct of clinical studies and PRO measures, supporting CDRH's goal of integrating standardized patient outcome measures into the regulatory process, and CDRH's participation in 12 collaborative communities, surpassing the target goal.

With regard to device safety, FDA highlighted the launch of the Safer Technologies Program, the extensive work on various cybersecurity safety measures, and the launch of the internal Decision Management Portal, including a medical device report (MDR) review workflow to improve the process flow for MDR review. CDRH has also continued work to increase material safety awareness, for example by releasing medical device safety summaries for materials commonly used in implantable devices, and took action to strengthen breast implant risk communication and help ensure that patients considering breast implants have adequate risk information to make informed decisions.

Finally, FDA highlighted quality and compliance initiatives, and developments in device policy, including proposing a landmark rule to establish a new category of over-the-counter hearing aids, and advancing device regulation and policy around digital health, including efforts to promote safe use of artificial intelligence/machine learning-enabled devices.

FDA responded to stakeholders' questions regarding funding for postmarket safety issues, integration of premarket and postmarket data systems for more efficient and informed review, and advantages of the new MDR review workflow within the internal Decision Management Portal.

Meeting End Time: 1:34 PM

Attendees:

Stakeholders

- Ryne Carney, *Alliance for Aging Research*
- Brandy Keys, *American Academy of Orthopedic Surgeons*
- Diana Clynes, *American Association of Kidney Patients*
- Paul Conway, *American Association of Kidney Patients*
- Catherine Hill, *American Association of Neurological Surgeons / Congress of Neurological Surgeons*
- Maria Gmitro, *Breast Implant Safety Alliance*
- Claire Ellis, *EveryLife Foundation for Rare Diseases*
- Amy Ohmer, *International Children's Advisory Network*
- Leanne West, *International Children's Advisory Network*
- Bennie Johnson, *Juvenile Diabetes Research Foundation International*
- Thomas Eagen, *National Center for Health Research*
- Jennifer Dexter, *National Health Council*
- Madris Kinard, *Patient Safety Action Network*
- Lisa McGiffert, *Patient Safety Action Network*
- Cynthia Bens, *Personalized Medicine Coalition*
- David Davenport, *Personalized Medicine Coalition*
- Cara Tenenbaum, *Postpartum Pelvic Health Advocates*

FDA

- Lauren Roth, *OC OP, Lead Negotiator*
- Cherron Blakely, *CDRH*
- Kathryn Capanna, *CDRH*
- Josh Chetta, *CDRH*
- Misti Malone, *CDRH*
- Michelle Tarver, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Jennifer Tomasello, *CDRH*
- Nia Benjamin, *CDRH*
- Marta Gozzi, *CDRH*
- Mimi Nguyen, *CDRH*
- Kimberly Kopecki, *CDRH*