U.S. FOOD & DRUG ADMINISTRATION

Office of Orthopedic Devices (OHT6) 2019 Update

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OSMA Summer Meeting

July 24, 2019

Outline

- OHT6 Staffing Updates
- Future Activities
- OSMA Questions

OHT6 Staffing Updates

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Currently interviewing for 3 Division Directors and 2 Assistant Directors

Onboarding around 20 new review staff hires, including Project Managers, Engineers, Microbiologists, Epidemiologists, DVMs and MDs

Future Activities

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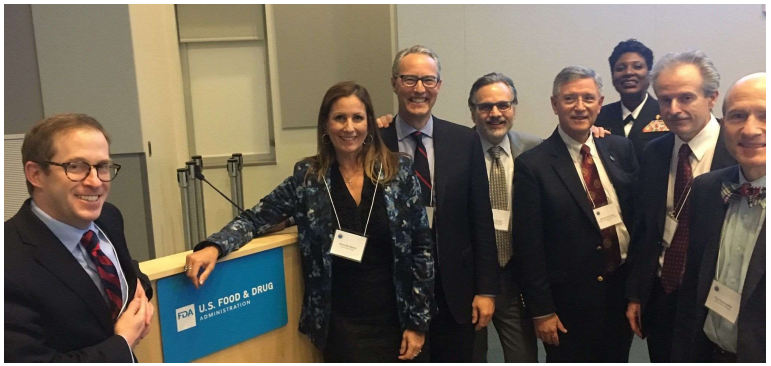
FDA Reviewers to attend a **CHOP training course** in September 2019



OHT6 is working with the OrthoCRN planning committee to hold another **OrthoCRN** meeting (November 6, 2019) to discuss registries related to joint, spine and trauma

AAOS and FDA will be hosting an inaugural **Orthopedics Town Hall Meeting** (March 24, 2020) in Florida

OSMA Questions

OSMA Question 1

1. To what extent does the agency expect companies to police the personal social media sites of their employees? If an employee of a company were to share / like on their personal social media site third party user-generated content which is not part of any marketing campaign, and it contained inaccurate or misleading information, is the agency likely to hold the company accountable?

   Example: Bob sees a Facebook post with a TV News story about a device his company manufactures. During the TV news story, an individual makes unsubstantiated claims. Bob “likes” the story and shares it on his LinkedIn and Facebook pages. Is the company obligated to monitor this content or will they be held liable for promoting misleading information?

OSMA Question 1 Feedback

FDA Response: The Food, Drug and Cosmetic Act provides that a device is misbranded or adulterated if the device advertising or labeling are false or misleading, or if it changes the product's intended use/indications for use. The example described in the question above pertains to personal social media site visits of a manufacturer's employees, and FDA does not have particular statutory authority over a company's role with regard to the personal social media sites of its employees. The relationship between a company and its employees in this area, as in many others, can raise issues better addressed on a case-by-case basis. With this said, it may be helpful to have training and education offered to employees to make them aware of how to identify and handle inaccurate or misleading information that they come across; although not final, FDA has published a draft guidance, Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices , that outlines our recent consideration on this topic, and provides some guidelines that might be helpful if a manufacturer elects to correct independent third-party misinformation.

OSMA Question 2

2. We are aware the 510(k) reviewers are searching the MAUDE database while conducting premarket reviews. How are these searches being done – by predicate brand name or by more broadly by FDA Product Code?

   How does the agency reconcile this use of the database when the MAUDE website states:
   "…this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data" and
   "Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated."

OSMA Question 2 Feedback

FDA Response: There are a variety of methods that reviewers use to conduct MDR searches, including by trade name, generic name, product code and typographical variants. We do take into account the limitations of passive surveillance, but there have been valuable safety signals identified through this type of analysis both in orthopedics as well as other OPEQ product areas.

OSMA Question 3

3. Does FDA feel it will need to review summary of safety and clinical performance (SSCP) documents for Class II devices?

OSMA Question 3 Feedback

FDA Response: The SSCP is a requirement for the European Medical Device Regulations (MDR) and apply to Class III and implantable devices under their system, and is not a requirement imposed by FDA. With this said, if the SSCP is included as part of a pre-market submission, such as a 510(k), the Lead Reviewer may look at this information.

OSMA Question 4

4. Will labeling modifications that are required for MDR (e.g. patient implant card and CMR labeling) require submission of a 510(k) to the FDA or can it be documented internally?

OSMA Question 4 Feedback

FDA Response: It is recommended that you consult the document, Deciding When to Submit a 510(k) for a Change to an Existing Device - Guidance for Industry and FDA Staff, to determine whether or not a 510(k) submission is needed for any labeling modifications that are required for MDR (e.g., patient implant card and CMR labeling), as the extent of changes made from the existing labeling within a cleared 510(k) will likely dictate the need for a new premarket submission. When the interpretation is unclear, we are available to provide input on the proposed modifications.

Thank you