Regulation of Dermal Fillers

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Classification

- Class III device
- Approved through the PMA process
- Each device must demonstrate stand alone safety and effectiveness
- Product codes
  - LMH: implant, dermal, for aesthetic use
  - PKY: implant, dermal, for aesthetic use in the hands

Premarket Approval (PMA) Process

During PMA application review the FDA reviews the following to make a final benefit/risk determination:

- Quality System Inspection(s) and Bioresearch Monitoring (BIMO) Audit (audit of clinical study data) conducted by FDA personnel
- Substantive review of:
  - Nonclinical Studies
  - Clinical Studies
  - Labeling: Clinician and Patient

Preclinical Evidence

- Materials chemistry characterization
- Drug distribution, release, and stability (if product contains lidocaine)
- Characterization of syringe and injections methods (i.e., needle and/or cannula)
- Sterility
- Biocompatibility
- Manufacturing

Clinical Evidence

- Clinical trials conducted in the US are approved by FDA prior to study initiation through the investigational device exemption (IDE) program
- Studies vary in design based on the objective of the study and:
  - Proposed indications for use
  - If the dermal filler has been previously approved for another indication
  - Material properties of the filler, including cross-linking, stiffness, and anticipated duration of effect

Clinical Evidence

Safety evaluation typically includes:

- Collection of injection site reactions or common treatment responses through the use of a subject safety diary lasting 2-4 weeks
- Adverse events are also collected throughout the study and the incidence, severity, duration, relatedness, and resolution are recorded.
- Indication-specific assessments may also be included (such as hand functionality, speech, lip functionality, ability to smile broadly, etc.)

The safety evaluations to actively and deliberately monitor for visual impairment will be discussed later by Dr. Henry Lee.

Clinical Evidence

Effectiveness evaluation

- New indications for use continue to emerge, including augmentation and contouring
- Previous methods of assessing effectiveness may not be applicable
- Typically a combination of clinician- and patient-reported outcomes
- The end user (patient) makes a decision about treatment
  - It is important that the information that matters to the patient is communicated

Post-Approval Actions

- Post-Approval Study (PAS)
  - 2015 Advisory Committee Meeting
    - Panel recommended additional studies to evaluate the effect of dermal filler on hand function, hand imaging, and the safety and effectiveness in patients with more severe volume loss
    - Two post-approval studies were conducted per panel recommendations
- PMA annual report review
- Review of medical device reports
- Labeling updates

Panel Discussion

The panel will be asked today to make recommendations on the regulation of dermal fillers at different stages of product development and approval.

This includes discussion of clinical study considerations, appropriate labeling information as part of the informed decision-making process, and how to incorporate critical safety elements as well as patient perspective into the assessment of dermal filler products.


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