FDA Questions

March 23, 2021

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting

Dermal Filler General Issues

Risks Associated with Unintentional Intravascular Injection of Dermal Fillers

1. Currently, clinical studies include vision assessments to actively and deliberately monitor for intravascular injection in all patients receiving dermal filler regardless of the indication for use or risk associated with the injection area. Is this strategy appropriate, or do you recommend the approach be revised such that active and deliberate monitoring is conducted in clinical studies for:
    - All patients receiving dermal filler in anatomic areas with more reports of vascular occlusion-related events, or
    - Only patients who exhibit symptoms of vascular occlusion or vision-related complications after injection?

    Are there other circumstances or factors, such as injection volume, that would modify the approach?

2. For PMA-approved devices, do you recommend that vision assessments be required to actively and deliberately monitor for intravascular injection, before and after injection in all patients receiving dermal fillers, or are there circumstances where monitoring for visual impairment is not needed?

3. Postmarket evaluation of vision and neurologic abnormalities in a larger subject population, such as through post-approval studies, may help to characterize the risk associated with intravascular injection into a blood vessel. In what specific indications or situations would you recommend such post-approval studies be required?

4. What steps can manufacturers and professional societies take to educate providers on risk factors for intravascular injection and the strategies that can be employed to mitigate risk?

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Patient Preference and Informed Decision Making

5. Development of publicly available validated effectiveness measures, and use of these measures in premarket dermal filler studies, would facilitate standardized evaluations with uniform endpoints and success measures, permitting comparison of effectiveness outcomes across dermal fillers.

    a. Do you have recommendations on how to encourage both the development of publicly available measures and the use of these measures in dermal filler studies?

    b. Are there additional measures, resources, or tools that would allow patients as well as clinicians to compare products for a similar indication and to address patient's expectations?

6. FDA recognizes the importance of incorporating diverse subject populations in clinical studies, and in the development of validated outcome measures. To this end, FDA has recommended that clinical studies enroll patients with all Fitzpatrick skin types. However, given the diversity of patients with respect to age, race, and gender, as well as differences in individual risk tolerance i.e., patient preference, we have the following questions:

    a. In addition to Fitzpatrick skin types, do you recommend defining additional patient populations for clinical study enrollment and the development of valid, clinically relevant effectiveness measures?

    b. How do you recommend the appropriate patient populations be identified, and what factors or data do you recommend be considered in determining the appropriate patient populations?

7. FDA proposes the proactive incorporation of patient preference information (PPI) into the design of clinical studies and the approval process. This may include the incorporation of study endpoints that query participants regarding the level of risk that is acceptable to achieve various levels of perceived benefit (e.g., filling of an age-related wrinkle, augmentation of the lips, improvement of the profile of the chin).

    a. Does the Panel have recommendations regarding how to incorporate study participants' tolerance for risk at different levels of benefit in the benefit/risk assessment of a dermal filler?

    b. Since factors such as demographics may affect patient preference, what factors should be considered when incorporating PPI into clinical studies and the benefit/risk assessment of dermal fillers?

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8. FDA believes that it's important for patients to be appropriately informed of the benefits and risks of dermal fillers.

    a. Are the current methods of informing patients adequate, or are additional strategies needed to appropriately convey risks of dermal filler injections to patients, particularly for areas with more reports of vascular occlusion-related events?

    b. FDA has identified the following examples that may be useful strategies to communicate the benefits and risks of dermal filler injections to patients:

        i. Patient labeling with consistent presentation of benefits and risks, with specific structure and content
            1. Patient labeling that includes additional information on increased risks for areas with more reports of vascular-occlusion related events

        ii. A boxed warning regarding the risk of intravascular injection

        iii. A patient decision checklist that, among other information, may include:
            1. information and risks for dermal filler injections
            2. specific mention of the risks of soft tissue necrosis, blindness, and stroke
            3. additional information and acknowledgment of risks for areas with more reports of vascular occlusion-related events, if these areas are approved through the PMA process
            4. an approach for patients and providers to affirmatively acknowledge that each item was read and discussed

    If you believe that additional strategies are needed, would you recommend that the example strategies above be implemented or that alternative or additional strategies be implemented?

9. Would you recommend that a patient device card be part of the patient labeling? Does the proposed mock-up card example below have sufficient information?