GENERAL AND PLASTIC SURGERY DEVICES PANEL
OF THE MEDICAL DEVICES ADVISORY COMMITTEE

Food and Drug Administration – Hilton Washington DC
North Gaithersburg, MD
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PANEL QUESTIONS - DAY 2

In the previous presentation, FDA described three categories of wound dressings combined with drugs:

1) Solid Wound Dressings combined with Drugs,
2) Wound Dressings combined with Drugs formulated as a Cream, Gel, or Ointment, and
3) Liquid Wound Washes combined with Drugs.

For the remainder of the day, you will be asked to address a set of questions for each of the three categories. As you respond to the following questions, please remember the definition of each wound dressing category.

Solid Wound Dressings combined with Drugs

1. For Solid Wound Dressings combined with Drugs, FDA has identified the following risks to health based upon review of: the medical literature, information available to FDA on cleared products, and the Medical Device Report databases. Please comment on whether you agree with the Potential Risks to Health presented below and identified in the overall risk assessment of these products within the product code FRO. In addition, please comment on whether any additional risks should be included in this overall risk assessment of Solid Wound Dressings combined with Drugs under the product code FRO.

Dressing Type	Potential Risks to Health
Solid wound dressings	• Adverse tissue reaction (e.g., toxicity, allergic reaction, irritation and sensitization) • Delays in wound healing • Incompatibilities with other therapies • Increased risk of contributing to antimicrobial resistance • Infection • Loss of barrier function • Microbial growth within the product • Product degradation during storage • Retention of dressing material in wound

2. For Solid Wound Dressings combined with Drugs, the risk/mitigation table below outlines the identified risks to health and potential regulatory controls/data requirements that FDA could apply for each identified risk. Please discuss each of these potential controls and whether it, either alone or in combination with others, adequately mitigates the identified risk(s).

Identified Risk	**Potential Mitigation Measure**
Adverse tissue reaction	• Biocompatibility evaluation
Delays in wound healing	• *In vivo* evaluation
Incompatibilities with other therapies	• Labeling
Increased risk of contributing to antimicrobial resistance	• Evaluation and identification of the risk and potential mechanisms for resistance development • Labeling
Infection	• Labeling • Shelf-life validation • Sterilization validation • Preservative effectiveness testing
Loss of barrier function	• Microbial barrier effectiveness testing • Water loss/moisture barrier effectiveness testing
Microbial growth within a product	• Antimicrobial effectiveness testing
Product degradation during shelf storage	• Labeling • Shelf-life validation
Retention of dressing material in wound	• Labeling

3. Section 513 of the Food, Drug, and Cosmetic Act states that a device is Class III if:

   - insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness AND insufficient information exists to determine that application of special controls would provide such assurance, AND

   - the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or the device presents a potential unreasonable risk of illness or injury.

A device should be Class II if:

- general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness, AND
- there is sufficient information to establish special controls to provide such assurance.

A device should be Class I if:

- general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
- insufficient information exists to:
  - determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
  - establish special controls to provide such assurance, BUT
    - the device is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, AND
    - it does not present a potential unreasonable risk of illness or injury.

a. FDA believes that general controls, by themselves, are insufficient to provide a reasonable assurance of product safety and effectiveness. For Solid Wound Dressings combined with Drugs please comment on whether:

   i. sufficient information exists to establish special controls to adequately mitigate the risks to health and provide a reasonable assurance of device safety and effectiveness for this device type;

   ii. the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or the device presents a potential unreasonable risk of illness or injury.

b. For the category of Solid Wound Dressings combined with Drugs, please provide a recommendation regarding which products should be classified into Class II or into Class III? Please discuss the reasons for your recommendation.

Wound Dressings combined with Drugs formulated as a Cream, Gel, or Ointment

4. For Wound Dressings combined with Drugs formulated as a Cream, Gel, or Ointment, FDA has identified the following risks to health based upon review of: the medical literature, information available to FDA on cleared products, and the Medical Device

Report databases. Please comment on whether you agree with the Potential Risks to Health presented below and identified in the overall risk assessment of these products within the product code FRO. In addition, please comment on whether any additional risks should be included in this overall risk assessment of a Wound Dressing combined with Drugs formulated as a Cream, Gel, or Ointment under the product code FRO.

Dressing Type	**Potential Risks to Health**
Creams, gels, ointments	• Adverse tissue reaction • Delays in wound healing • Incompatibilities with other therapies • Increased risk of contributing to antimicrobial resistance • Infection • Microbial growth within a product • Product degradation during shelf storage

5. For Wound Dressings combined with Drugs formulated as a Cream, Gel, or Ointment, the risk/mitigation table below outlines the identified risks to health and potential regulatory controls/data requirements that FDA could apply for each identified risk. Please discuss each of these potential controls and whether it, either alone or in combination with others, adequately mitigates the identified risk(s).

Identified Risk	**Potential Mitigation Measure**
Adverse tissue reaction	• Biocompatibility evaluation
Delays in wound healing	• *In vivo* evaluation
Incompatibilities with other therapies	• Labeling
Increased risk of contributing to antimicrobial resistance	• Evaluation and identification of the risk and potential mechanisms for resistance development • Labeling
Infection	• Sterilization validation • Preservative effectiveness testing • Shelf-life validation • Labeling
Microbial growth within product	• Antimicrobial effectiveness testing
Product degradation during shelf storage	• Shelf-life validation • Labeling

6. Consistent with Section 513 of the FD&C Act, please consider the following:

    a. FDA believes that general controls, by themselves, are insufficient to provide a reasonable assurance of product safety and effectiveness. For Wound Dressings

combined with Drugs formulated as a Cream, Gel, or Ointment**,** please comment on whether:

i. sufficient information exists to establish special controls to adequately mitigate the risks to health and provide a reasonable assurance of device safety and effectiveness for this device type;

ii. the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or the device presents a potential unreasonable risk of illness or injury.

b. For the category of Wound Dressings combined with Drugs formulated as a Cream, Gel, or Ointment, please provide a recommendation regarding which products should be classified into Class II or into III? Please discuss the reasons for your recommendation

Liquid Wound Washes combined with Drugs

7. For Liquid Wound Washes combined with Drugs, FDA has identified the following risks to health based upon review of: the medical literature, information available to FDA on cleared products, and the Medical Device Report databases. Please comment on whether you agree with the Potential Risks to Health presented below and identified in the overall risk assessment of these products within the product code FRO. In addition, please comment on whether any additional risks should be included in this overall risk assessment of Liquid Wound Washes combined with Drugs under the product code FRO.

Dressing Type	Potential Risks to Health
Liquid wound washes	• Adverse tissue reaction • Delays in wound healing • Inability to remove wound debris and foreign materials • Incompatibilities with other therapies • Increased risk of contributing to antimicrobial resistance • Infection • Microbial growth within product • Product degradation during shelf storage

8. For Liquid Wound Washes combined with Drugs, the risk/mitigation table below outlines the identified risks to health and potential regulatory controls/data requirements that FDA could apply for each identified risk. Please discuss each of these potential controls and whether it, either alone or in combination with others, adequately mitigates the identified risk(s).

Identified Risk	**Potential Mitigation Measure**
Adverse tissue reaction	• Biocompatibility evaluation
Delays in wound healing	• *In vivo* evaluation
Loss of barrier function	• Microbial barrier effectiveness testing • Water loss/moisture barrier effectiveness testing
Inability to remove wound debris and foreign materials	• Labeling • Bench performance testing
Incompatibilities with other therapies	• Labeling
Increased risk of contributing to antimicrobial resistance	• Evaluation and identification of the risk and potential mechanisms for resistance development • Labeling
Infection	• Sterilization validation • Preservative effectiveness testing • Shelf-life validation • Labeling
Microbial growth within product	• Antimicrobial effectiveness testing
Product degradation during shelf storage	• Shelf-life validation • Labeling

9. Consistent with Section 513 of the FD&C Act, please consider the following:

    a. FDA believes that general controls, by themselves, are insufficient to provide a reasonable assurance of product safety and effectiveness. For Liquid Wound Washes combined with Drugs please comment on whether:

        i. sufficient information exists to establish special controls to adequately mitigate the risks to health and provide a reasonable assurance of device safety and effectiveness for this device type;

        ii. the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or the device presents a potential unreasonable risk of illness or injury.

    b. For the category of Liquid Wound Washes combined with Drugs, please provide a recommendation regarding which products should be classified into Class II or into Class III? Please discuss the reasons for your recommendation.