

V. Risks to Health

The Panel identified no risks to health associated with the use of silicone sheeting intended to manage hyperproliferative scars. They noted that the device is intended for use on intact skin and commented that no allergic reactions are associated with its use.

VI. Summary of the Data Upon Which the Proposed Recommendation is Based

The Panel based its recommendation on the information provided by FDA, the presentations made by manufacturers and FDA at the Panel meeting, the open discussion during the Panel meeting, and the Panel members' personal knowledge of and clinical experience with the device.

VII. FDA's Tentative Findings

FDA tentatively agrees with the recommendation of the Panel that silicone sheeting intended to manage hyperproliferative scars on intact skin should be classified into class I because the agency believes that sufficient information exists to determine that general controls would provide reasonable assurance of safety and effectiveness.

FDA tentatively disagrees with the recommendation of the Panel that silicone sheeting meets the reserved criteria of new section 510(1) of the act and that it should be a prescription device. FDA does not believe that the device is of substantial importance in preventing impairment of human health or that it presents a potential unreasonable risk of illness or injury, and therefore has determined that it should be exempt from premarket notification. FDA also has determined that prescription use of the device is unnecessary.

FDA notes that four wound dressing products that are intended to cover wounds on non-intact skin currently are adequately regulated as class I devices that are exempt from premarket notification procedures and as nonprescription use devices. These devices are the nonresorbable gauze/sponge for external use (21 CFR 878.4014), the hydrophilic wound dressing (21 CFR 878.4018), the occlusive wound dressing (21 CFR 878.4020), and the hydrogel wound and burn dressing (21 CFR 878.4022). Because silicone sheeting is intended for use on intact skin, the agency believes that the same regulatory control that reasonably assures the safety and effectiveness of these four wound dressings intended for use on non-intact skin, i.e., regulation as a

nonprescription use class I device exempt from premarket notification, is adequate to reasonably assure the safety and effectiveness of silicone sheeting. Therefore, the agency is proposing that silicone sheeting intended to manage hyperproliferative scars on intact skin be classified into class I and that it be exempt from premarket notification.

VIII. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed classification is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Public Law 96-354) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104-121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages, distributive impacts, and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. As noted previously, FDA may classify devices into one of three regulatory classes according to the degree of control needed to provide reasonable assurance of safety and effectiveness. FDA is proposing that this device be classified into class I, the lowest level of control allowed. In addition, FDA is proposing to exempt it from premarket notification requirements. The agency, therefore, certifies that this proposed rule will not have a significant impact on a substantial number of small entities. In addition, it will not impose costs of \$100 million or more on either the private sector or State, local, and tribal

governments in the aggregate, and therefore, a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) is not required.

XI. Submission of Comments and Proposed Dates

You may submit to the Dockets Management Branch written or electronic comments regarding this proposal. You must submit two copies of any mailed comments, except that individuals may submit one copy. You should identify comments with the docket number found in brackets in the heading of this document. Comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA proposes that any final rule that may issue based on this proposal become effective 90 days after its date of publication in the **Federal Register**.

XII. Reference

The following reference has been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. General and Plastic Surgery Devices Panel, meeting transcript, pp. 1-82, July 8, 2001.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878 be amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 878.4025 is added to subpart E to read as follows:

§ 878.4025 Silicone sheeting.

(a) *Identification.* Silicone sheeting is intended to manage hyperproliferative (hypertrophic and keloid) scars on intact skin.

(b) *Classification.* Class I (general controls). The device is exempt from the